



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,613	07/18/2005	Seung-seob Lee	4684-025	7335
23429 7590 09/15/2008 LOWE HAUPTMAN HAM & BERNER, LLP 1700 DIAGONAL ROAD SUITE 300 ALEXANDRIA, VA 22314				
EXAMINER				
OCHYLSKI, RYAN M				
ART UNIT		PAPER NUMBER		
4151				
MAIL DATE		DELIVERY MODE		
09/15/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/542,613

Applicant(s)

LEE ET AL.

Examiner

RYAN OCHYLSKI

Art Unit

4151

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☒ Claim(s) 1 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Drawings

1. The drawings are objected to because of the following reasons:
2. Figure 1 includes a label for Item 12, but Item 12 is not defined in the paragraph describing Figure 1 (Page 5 Lines 1-4).
3. Figure 2b includes a label for Item 2, but Item 2 is not defined in the paragraph describing Figure 2b (Page 5 Lines 13-19).
4. Figure 4a does not include a label for Item 1, but Item 1 is references in the paragraph describing Figure 4a (Page 6 Lines 26-29).
5. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The abstract of the disclosure is objected to because it contains 172 words. Correction is required. See MPEP § 608.01(b).
7. The disclosure is objected to because of the following informalities: Replace "PMMS" with --PMMA-- on Page 7 Lines 3 and 6.

Claim Objections

8. Claim 1 is objected to because of the following informalities: PDMS and PMMA should be fully spelled out on their first occurrence in the claims. Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sherman et al. (US 6,451,240) in view of Prausnitz et al. (WO 99/64580) and in further view of Wood et al (US 6,511,463).

13. Regarding Claim 1, Sherman et al. teach a method for manufacturing a micro needle array, comprising the steps of preparing an X-ray mask by forming an absorber having a configuration of the micro needle array on a substrate; preparing a PMMA cast for the micro needle array by exposing PMMA to vertical X-rays using the X-ray mask (Column 34 Lines 45-56); filling an upper surface of a mold having configuration opposite to that of the PMMA cast with a gel type of polymer to obtain a desired thickness of the polymer (Column 35 Lines 30-52); and separating the mold to complete the polymer micro needle array (Column 35 Lines 53-59). While Sherman et al. does

not specifically recite a gel type of polymer, a skilled artisan would understand that readily deformable polymer material is equivalent to a gel type polymer.

However, Sherman et al. do not teach that a flexible PDMS mold is prepared pouring PDMS on the PMMA cast; or patterning a desired configuration of a hole by irradiating UV rays on the polymer.

In analogous art pertaining to the manufacture of micro needles, Prausnitz et al. denote a teaching of a flexible PDMS mold is prepared pouring PDMS on a cast (Page 20 Line 25 - Page 21 Line 19) and patterning a desired configuration of a hole by irradiating UV rays on the polymer (Page 18 Lines 14-15) for the benefit of easier removal and reuse of the micro needle mold, and more precise etching that allows for more efficient fluid collection. While Prausnitz et al. does not specifically recite irradiating UV rays, a skilled artisan would understand that UV irradiation exposure is a type of patterning through photoresist that would be arrived at through routine experimentation.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine Sherman et al. with Prausnitz et al. for the benefit of easier removal and reuse of the micro needle mold, and more precise etching that allows for more efficient fluid collection.

However, the previous combination does not teach exposing the cast to inclined X-rays.

In analogous art pertaining to the manufacture of micro needles, Wood et al. teach exposing a cast to inclined x-rays (Column 6 Lines 28-31) for the benefit of shaping the tip of micro needles to prevent clogging.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the previous combination with Wood et al. for the benefit of shaping the tip of micro needles to prevent clogging.

14. Regarding Claim 2, Sherman et al. teach patterning the configuration of the micro needle array using a photosensitive polymer, a developer, and an etchant (Column 34 Lines 51 - Column 35 Line 5)

However, Sherman et al. do not teach forming an insulating layer by forming an oxide layer (SiO_2) on the substrate, forming a base substrate for electroforming by depositing a metal layer on the insulating layer, or forming the X-ray absorber by electroforming an Au layer using the patterned photosensitive polymer and removing the patterned photosensitive polymer.

In analogous art pertaining to the manufacture of micro needles, Prausnitz et al. teach forming an insulating layer by forming an oxide layer (SiO_2) on the substrate (Page 16 Line 27 - Page 17 Line 1 and Page 19 Lines 30-31), forming a base substrate for electroforming by depositing a metal layer on the insulating layer (Page 21 Lines 9-10), and forming the X-ray absorber by electroforming an Au layer using the patterned photosensitive polymer and removing the patterned photosensitive polymer (Page 21 Lines 10-14) for the benefit of forming tapered micro needles for better fluid flow characteristics while minimizing the size of punctures made in the skin.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine Sherman et al. with Prausnitz et al. for the benefit of forming tapered micro needles for better fluid flow characteristics while minimizing the size of punctures made in the skin.

However, the previous combination does not teach depositing a Cr/Au layer.

In analogous art pertaining to the manufacture of micro needles, Wood et al. teach depositing a Cr/Au metal layer (Column 6 Lines 59-67) for the benefit of better gold bonding.

Therefore, it would have been obvious to a person having ordinary skill in the art at the time of the invention to combine the previous combination with Wood et al for the benefit of better gold bonding.

15. Regarding Claim 3, Sherman et al. further teach that the substrate comprises a silicon substrate (Column 34 Lines 37-45).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RYAN OCHYLSKI whose telephone number is (571)270-7009. The examiner can normally be reached on Monday through Thursday from 7:30-5:00 and every other Friday from 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Ortiz can be reached on 571-272-1206. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

rmo

***/Angela Ortiz/
Supervisory Patent Examiner, Art Unit 4151***